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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/766,547	01/19/2001	Dilip Wagle	361331-501	9923
30623	7590	11/01/2004	EXAMINER	
MINTZ, LEVIN, COHN, FERRIS, GLOVSKY AND POPEO, P.C. ONE FINANCIAL CENTER BOSTON, MA 02111			SHIAO, REI TSANG	
			ART UNIT	PAPER NUMBER
			1626	

DATE MAILED: 11/01/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

# Office Action Summary

Application No.

09/766,547

Applicant(s)

WAGLE ET AL.

Examiner

Robert Shiao

Art Unit

1626

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --  
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

## Status

- 1) ☒ Responsive to communication(s) filed on responses filed on 09/03, 2004.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

## Disposition of Claims

- 4) ☒ Claim(s) 1-17 is/are pending in the application.
- 4a) Of the above claim(s) 12-17 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-11 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

## Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

## Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
  - ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

## Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)  
Paper No(s)/Mail Date 06/27/02, 7/11/03.
- 4) ☒ Interview Summary (PTO-413)  
Paper No(s)/Mail Date. \_\_\_\_\_.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: \_\_\_\_\_.

### **DETAILED ACTION**

1. This application claims benefit of the provisional application: 60/176,995 with a filing date 01/19, 2000; and 60/183,274 with a filing date 02/17, 2000.
2. Amendment of claims 1, 7-9, withdrawal of claims 2-3, 12-17, cancellation of claims 18-25 in the amendment filed on September 03, 2004, is acknowledged. Claims 1-17 are pending in the application.

### ***Responses to Election/Restriction***

3. Applicant's election with traverse of Group IV claims 1-11, in part, in the reply filed on September 03, 2004, is acknowledged. The traversal is on the grounds that (1) the compounds of formula (I) or (IA) defined in the claims all have a related core structure; (2) the Examiner did not demonstrate the search of the separate claims presents an undue burden on the Examiner, and M.P.E.P 808.02 is cited. However, during a telephone conversation with Mathew J. Golden on September 16, 2004, a revised election was made with traverse to prosecute the invention of Group I, claims 1-11, in part. Claims 12-17 are withdrawn from further consideration by the examiner, 37 CFR 1.142(b), as being drawn to a non-elected invention. This is not found persuasive, and reasons are given, *infra*.

### ***Status of the Claims***

4. Claims 1-17 are pending in the application. The scope of the invention of the elected subject matter is as follows:

Claims 1-11, in part, drawn to methods of use (i. e., treating damage to blood vasculature, atherosclerosis, peripheral vascular disease, coronary heart disease or heart failure) of a compound of formula (I or IA), wherein the variable J represents sulfur thereof; the bond between carbons 4 and 5 is a single bond or a double bond; wherein  $R^a$  and  $R^b$  independently do not represent heteroaryl or heterocycle (i.e., morpholine, piperidine, etc),  $R^a$  and  $R^b$  together with their ring carbons can form a  $C_6$ - or  $C_{10}$  aryl fused ring thereof,  $R^a$  and  $R^b$  together with their ring carbons do not form a fused 5- or 6-membered heteroaryl ring,  $R^a$  and  $R^b$  together with their ring carbons do not form a fused 5- or 8-membered second heterocycle; the variables Ar and  $Ar^\phi$  of formula (I) do not independently represent 5- or 6-membered heteroaryl ring (i.e., pyrrolyl, furanyl, etc.) or heterocycle ring (i.e., piperidine, piperazine) thereof, and the variables Ar and  $Ar^\phi$  are not independently substituted with 5- or 6-membered heteroaryl ring or heterocycle ring; the variables  $R^c$ ,  $R^e$ , or  $R^f$  independently do not represent or independently are not substituted with 5- or 6-membered or 9- or 10-membered heteroaryl ring or heterocycle ring, i.e., formula (II), formula (IV), pyrrolidinyl, piperazine, piperidine, etc.

The above mentioned withdrawn compounds which are withdrawn from consideration as being for non-elected subject matter differ materially in structure and composition from the compounds of the elected invention. The withdrawn compounds contain varying functional groups (i.e., heteroaryl or heterocycle) which differ from those of the elected invention such as piperazine, morpholine, pyridazine, pyrimidine, etc, which are chemically recognized to differ in structure and function. This recognized

chemical diversity of the functional groups can be seen by the various classification of these functional groups in the U.S. classification system, i.e., class 544 subclass 358(+) (piperazine), class 544 subclass 106(+) (morpholine), class 544 subclass 224 (+) (pyridazine), class 544 subclass 242 (+) (pyrimidine), etc. Therefore, again, the compounds which are withdrawn from consideration as being for non-elected subject matter differ materially in structure and composition and have been restricted properly.

The Markush group set forth in the claims includes both independent and distinct inventions, and patentably distinct compounds (or species) within each invention. However, this application discloses and claims a plurality of patentably distinct inventions far too numerous to list individually. Moreover, each of these inventions contains a plurality of patentably distinct compounds, also far too numerous to list individually.

The inventions are independent and distinct because there is no patentable co-action between the groups and a reference anticipating one member will not render another obvious. Each group is directed to art recognized divergent subject matter which require different searching strategies for each group. Moreover, the examiner must perform a commercial database search on the subject matter of each group in addition to a paper search, which is quite burdensome to the examiner.

The invention claims 1-11, in part, embraced in above elected subject matter are prosecuted in the case. Claims 1-11, in part, not embraced in above elected subject matter, and claim 12-17 are withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected invention.

The requirement is still deemed proper and is therefore made **FINAL**.

***Claim Rejections - 35 USC § 102***

5. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1-11 are rejected under 35 U.S.C. 102(b) as being anticipated by Foulkes US 5,580,722, see CAS: 126:102570.

Applicant claim a compound of formula (I) or (IA) as agents treating heart diseases or heart failure, and this compound is found in the pages 2-16 of the specification.

Foulkes et al. disclose a compound 2-Thiazolamine as an agent for cardiovascular disease, clearly anticipate the instant compound of formula (I), wherein the variable J represents sulfur, the carbon 2 to nitrogen bond is a double bond; variables R<sup>a</sup> and R<sup>b</sup> independently represents hydrogen; the variable R<sup>c</sup> represents amino, see RN:96-50-4 of DN: 126:102570.

***Double Patenting***

6. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent

and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

7. Claims 1-11 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claim 1 of Wagle et al. US 6,596,744. Although the conflicting claims are not identical, they are not patentably distinct from each other and reasons are as follows.

Applicant claim a compound of formula (I) or (IA) as agents treating heart diseases, arteriosclerosis, peripheral vascular disease, coronary heart disease, or diabetes, and this compound and the methods of use are found in the pages 2-16 of the specification.

Wagle et al. claim a compound of formula (I) or (IA) as agents treating heart diseases, arteriosclerosis, peripheral vascular disease, coronary heart disease, or diabetic nephropathy, and a number of methods of use have been specifically exemplified, see columns 5-16, and 28-32.

The difference between the instant claims and Wagle et al. is that the instant methods of use are not for treating amyotrophic lateral sclerosis.

One having ordinary skill in the art would find the instant claims *prima facie* obvious **because** one would be motivated to employ the methods of Wagle et al. to obtain the instant methods of use, wherein a compounds of formula (I) or (IA) is used for treating heart diseases, arteriosclerosis, peripheral vascular disease, coronary heart disease, or diabetes.

The motivation to make the claimed compounds derives from the expectation that the instant claimed methods of use of compounds of formula (I) or (IA) would possess similar activity, i.e., agents treating heart diseases or arteriosclerosis, from the known Wagle et al. methods using similar compounds of formula I or (IA) to that which is claimed in the reference.

### ***Objection***

8. Claims 1-11 are objected to as containing non-elected subject matter, i.e., heteroaryl, heterocycle, formula (II), formula (IV), triazole, tetrazole, pyrrolidine, pyridine, piperidine, morpholine, etc. It is suggested that applicants amend the claims to the scope of the elected subject matter as defined on the elected subject matter of pages 2-3, *supra*.

9. Claim 6, lines 3-5, is objected. It appears there are typographic errors between each compound. Replacement of the symbol “,” with the symbol”,” between each compound would obviate the objection.

### ***Telephone Inquiry***

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Robert Shiao whose telephone number is (571) 272-0707. The examiner can normally be reached on 8:30 AM - 5:00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Joseph K. McKane can be reached on (571) 272-0699. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

A handwritten signature in black ink, appearing to read "RDesai", with a horizontal line drawn underneath it.

Rita Desai  
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A handwritten signature in black ink, appearing to read "R. Shiao", written in a cursive style.

Robert Shiao, Ph.D.  
Patent Examiner  
Art Unit 1626

10/26/04.

October 25, 2004